UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. NOVADOZ PHARMACEUTICALS LLC, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, Defendants.	No. 25-CV-00849-EP-JRA

NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PLEASE TAKE NOTICE that Novadoz Pharmaceuticals LLC, MSN Pharmaceuticals Inc., and MSN Laboratories Private Limited, and hereby appeal to the United States Court of Appeals for the Third Circuit pursuant to 28 U.S.C. § 1292(a)(1) the Opinion and Order entered in the above captioned case by the United States District Court for the District of New Jersey granting Novartis AG and Novartis Pharmaceuticals Corporation's Motion for Preliminary Injunction dated March 17, 2025, ECF Nos. 32, 33. Copies of these rulings are attached hereto.

The Order granted Plaintiffs' request for preliminary injunctive relief and is therefore appealable as of right pursuant to 28 U.S.C. § 1292(a)(1). The Court of Appeals has jurisdiction to hear the appeal under 28 U.S.C. § 1292(a)(1).

Dated: March 24, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of March, 2025, I caused a copy of the foregoing to be served upon all counsel of record via ECF notification.

/s/ Rebekah Conroy
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NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS AG and NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. NOVADOZ PHARMACEUTICALS LLC, *et al.*, Defendants.	No. 25cv849 (EP) (JRA) **OPINION**

PADIN, District Judge.

This matter comes before the Court by way of Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation's (together, "Novartis") motion for a preliminary injunction against Defendants MSN Laboratories Private Limited, MSN Pharmaceuticals Inc., and Novadoz Pharmaceuticals LLC (collectively, "MSN") for alleged infringement of Novartis's trademark and trade dress rights. D.E. 4 ("Motion" or "Mot."). The Court decides the Motion without oral argument. *See* Fed. R. Civ. P. 78(b); L. Civ. R. 78.1(b). For the reasons set forth below, the Court will **GRANT in part** and **DENY in part** the Motion.

I. BACKGROUND

Novartis is a pharmaceutical company that manufactures ENTRESTO®, an FDA-approved heart failure prescription medication that was launched in 2015. D.E. 1 ¶¶ 3, 52-53 ("Compl."). It is the number one heart failure brand prescribed by physicians and has helped reduce the risk of

death and hospitalization for over 2.5 million patients. *Id.* ¶ 3. Novartis's generic partner is Sandoz, which used to be Novartis's wholly-owned generics division prior to its sale. *Id.* ¶ 7.

ENTRESTO® is offered in three doses, each in a unique combination of size, shape, and color. *Id.* ¶ 59. The Low Starting Dose, a 24/26 mg dose, is a violet white oval tablet, measuring 13.1 mm x 5.2 mm; the Recommended Starting Dose, a 49/51 mg dose, is a pale yellow oval tablet, measuring and 13.1 mm x 5.2 mm; and the Target Dose, a 97/103 mg dose, is a light pink oval tablet, measuring 15.1 mm x 6.0 mm. *Id.* Images of the drug show that the face of each pill is marked "NVR." D.E. 4-4 ¶ 15 ("Valazza Decl.").

Novartis alleges that MSN will imminently bring to market a generic version of ENTRESTO®, under the NOVADOZ name, intending to confuse healthcare providers and consumers into believing NOVADOZ is affiliated with Novartis (the "MSN Drug"). Compl. ¶¶ 6-7.

MSN submitted an Abbreviated New Drug Application ("ANDA") for its generic equivalent to ENTRESTO® on July 7, 2019. D.E. 13-7 ¶ 3 ("Nithiyanandam Decl."). To be eligible for FDA approval through an ANDA, a generic drug must contain the same active ingredient(s) of the branded drug, come in the same dosage form, and deliver the same dose. *Id.* ¶ 4. As a result, the MSN Drug also comes in three tablets: a 24/26 mg tablet, 49/51 mg tablet, and a 97/103 mg tablet. *Id.* ¶ 5. MSN's 2019 ANDA contained proposed dimensions of the drugs, respectively measuring 10 x 4 mm, 13 x 5.10 mm, and 15 x 5.9 mm. *Id.* ¶ 6. Images of the MSN

Drug show that the face of each pill is marked "M." *Id.* The pills are not identical, but strikingly similar.

PARAMETERS	REFERENCE LISTED DRUG	PROPOSED DRUG PRODUCT
Strengths	24 mg/ 26 mg, 49 mg / 51 mg and 97 mg/ 103 mg	24 mg/ 26 mg, 49 mg / 51 mg and 97 mg/ 103 mg
Configuration		
24 mg/ 26 mg, 49 mg / 51 mg and 97 mg/ 103 mg	Bottle of 60's and 180's	Bottle of 60's and 180's
24 mg/ 26 mg		
49 mg/ 51 mg		
97 mg/ 103 mg		
Dimensions		
24 mg/ 26 mg	13.35 x 5.33	10.00 X 4.00 mm
49 mg/ 51 mg	13.25 x 5.30	13.00 X 5.10 mm
97 mg/ 103 mg	15.34 x 6.12	15.00 X 5.90 mm
Active Ingredient	Sacubitril and Valsartan	Sacubitril and Valsartan

Id.

Novartis avers that the physical similarities between NOVADOZ and ENTRESTO®, as well as NOVADOZ's name—purportedly intended to invoke a combination of Novartis and Sandoz—reflects an intentional effort to deceive the marketplace. Compl. ¶ 7. The launch of NOVADOZ hinges on the lift of an injunction in place in a separate patent appeal pending before the Federal Circuit. *Id.* ¶ 89. MSN's counsel has "expressly communicated to Novartis's counsel that MSN will seek to launch the MSN Drug in the window between the issuance of the Federal Circuit's mandate, and the Delaware District Court's further orders once the case is returned after appeal." *Id.*

Novartis brings claims for trademark infringement, false designation of origin, trade dress infringement, and unfair competition. *Id.* ¶¶ 128-205. It argues that patients will face imminent health risks as the MSN drugs do not have FDA-approved dosing instructions and will be confused

with ENTRESTO®. Mot. at 3. Specifically, the ENTRESTO® label and prescribing information directs certain patients to start with a low starting dose, while the MSN drug label and prescribing information does not. *Id.* at 14-15. Novartis argues it will face reputational damage and loss of trade in the form of lost sales. *Id.* at 37.

II. PROCEDURAL HISTORY

Novartis's Motion also sought a temporary restraining order. Mot. This Court denied Novartis's request for temporary restraints but ordered expedited briefing on the preliminary injunction motion. D.E. 7. MSN's opposition, D.E. 13 ("Opp'n"), and Novartis's reply, D.E. 17 ("Reply"), followed.

III. LEGAL STANDARD

"Preliminary injunctions and TROs are extraordinary remedies that are not routinely granted." *Gentile v. Secs. and Exch. Comm'n*, No. 19-5155, 2019 WL 1091068, at *2 (D.N.J. Mar. 8, 2019) (citing *Kos Pharm., Inc. v. Andrx. Corp.*, 369 F.3d 700, 708 (3d Cir. 2004)). The decision to grant such relief is within the discretion of the district court. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

The primary purpose of preliminary injunctive relief is "maintenance of the status quo until a decision on the merits of a case is rendered." *Acierno v. New Castle Cnty.*, 40 F.3d 645, 647 (3d Cir. 1994). In order to obtain a TRO or a preliminary injunction, the moving party must show:

> (1) a reasonable probability of eventual success in the litigation, and (2) that it will be irreparably injured . . . if relief is not granted . . . . [In addition,] the district court, in considering whether to grant a preliminary injunction, should take into account, when they are relevant, (3) the possibility of harm to other interested persons from the grant or denial of the injunction, and (4) the public interest.

Reilly v. City of Harrisburg, 858 F.3d 173, 176 (3d Cir. 2017) (citing *Del. River Auth. v. Transamerican Trailer Transp., Inc.*, 501 F.2d 917, 919-20 (3d Cir. 1974)).

The movant bears the burden of establishing "the threshold for the first two 'most critical' factors . . . . If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief." *Id.* at 179. A court may issue an injunction to a plaintiff "only if the plaintiff produces evidence sufficient to convince the district court that all four factors favor preliminary relief." *AT&T v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1427 (3d Cir. 1994) (internal marks and citations omitted); *see also P.C. Yonkers, Inc. v. Celebrations the Party & Seasonal Superstore, LLC*, 428 F.3d 504, 508 (3d Cir. 2005) ("The burden lies with the plaintiff to establish every element in its favor, or the grant of a preliminary injunction is inappropriate.").

IV. ANALYSIS

A. Trade Dress

"A plaintiff must prove three elements to establish trade dress infringement under the Lanham Act: '(1) the allegedly infringing design is nonfunctional; (2) the design is inherently distinctive or has acquired secondary meaning; and (3) consumers are likely to confuse the source of the plaintiff's product with that of the defendant's product.'" *Fair Wind Sailing, Inc. v. Dempster*, 764 F.3d 303, 309 (3d Cir. 2014) (quoting *McNeil Nutritionals, LLC v. Heartland Sweeteners, LLC*, 511 F.3d 350, 357 (3d Cir. 2007)).

1. Novartis has adequately shown the ENTRESTO® trade dress is non-functional

"A nonfunctional feature is one that 'is unrelated to the consumer demand . . . and serves merely to identify the source of the product or business.'" *EBIN New York, Inc. v. Kiss Nail Prods., Inc.*, No. 23-2369, 2024 WL 1328029, at *6 (D.N.J. Mar. 28, 2024) (quoting *Fair Wind*, 764 F.3d at 311). "Conversely, a functional feature is 'one that is essential to the use or purpose of the article, affects the cost or quality of the article, or one that, if kept from competitors, would put

them at a significant non-reputation-related disadvantage.'" *Id.* (quoting *Fair Wind*, 764 F.3d at 310). In the case of drugs, "the allegedly nonfunctional element must not enhance efficacy." *SK & F, Co. v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055, 1063 (3d Cir. 1980).

MSN argues that communication of functional information to patients—what drug each pill is and what dose it contains—is evidenced by the colors and sizes of the ENTRESTO® pills. Opp'n at 13. It further indicates that consistent color-coding systems can reduce therapeutic errors in other drug regimens. D.E. 13-40 ¶ 53 ("Clark Decl."). Novartis attests that it is unaware of "any functional reason why the Low Starting Dose and the Recommended Starting Dose need to be smaller than the Target Dose. These sizes could be made uniform without impacting the efficacy of the formulation." Valazza Decl. ¶ 20. The selection of size and shape of the pills, therefore, was purely based on a desire to differentiate the tablets from competitors' trade dresses. *Id.* ¶ 16. And while ENTRESTO® comes in three doses, patients can progress up from the lower doses to the target dose. D.E. 4-11 ¶ 17 ("Nayeri Decl."). Patients typically take their tablets twice daily, indefinitely, irrespective of the dose on which they begin their regimens. *Id.* ¶ 18. There is no need to distinguish between daily doses, because once adjusted to a different dosage, patients remove the others from their medication cycle. Reply at 4 n.4.

Novartis's position, in sum, is that the ENTRESTO® Trade Dresses were designed to differentiate the drug in the heart failure treatment market, rather than to improve cost, quality, or efficacy. Mot. at 17. MSN counters that under Third Circuit precedent, color-coding of drugs to convey dosage information is functional. Opp'n at 12 (citing *Shire US Inc. v. Barr Labs., Inc.*, 329 F.3d 348 (3d Cir. 2003)).

On appeal in *Shire* was the lower court's finding that the color and shape of Adderall is non-functional, accepting the position of the generic's manufacturer that the similar color-coding

and shape of products are meaningful for ADHD patients and enhance efficacy. 329 F.3d at 354. The Third Circuit noted other cases crediting testimony bearing on functionality. In *Ives Labs., Inc. v. Darby Drug Co.*, 488 F. Supp. 394 (E.D.N.Y. 1980),[1] for example, the court found that the capsule colors of the prescription drug cyclandelate were functional because "many elderly patients associate the appearance of their medication with its therapeutic effect," "some patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions," and "to some limited extent color is also useful to doctors and hospital emergency rooms in identifying overdoses of drugs." *Id.* at 398-99. The Supreme Court also "commented on the functional nature of the color of medical pills," *Shire*, 329 F.3d at 358, in *Qualitex Co. v. Jacobson Prods. Co., Inc.*, 514 U.S. 159 (1995). The Court noted there that "competitors might be free to copy the color of a medical pill where that color serves to identify the kind of medication (*e.g.*, a type of blood medicine) in addition to its source." *Qualitex*, 514 U.S. at 169.

Novartis argues that *Shire* is distinguishable because it uniquely involved Adderall, a controlled substance; patients needed to distinguish between differing doses of Adderall throughout the day; and patients with ADHD rely on visual cues in making dosing adjustments. Reply at 4. As the lower court did in *Shire*, this Court will assess and credit testimony as it pertains to the facts of this case specifically. For the reasons below, it finds that *Shire* is distinguishable.

The parties' experts have competing but overlapping arguments for why a pill's distinctive (or similar) appearance is important for patients. Novartis's expert notes that drug shape and color can be helpful for patients to identify their prescriptions. D.E. 4-10 ¶ 13 ("Robbins Decl."). Drug

[1] The Supreme Court granted certiorari and reversed the judgment of the Second Circuit, which had reversed the district court.

appearance is particularly important for patients with chronic conditions such as chronic heart failure because they are more familiar with an appearance of a medication they take repeatedly, over a long period of time, and patients with chronic conditions are more likely to take multiple medications relative to others. *Id.* ¶ 14. Dr. Mark Robbins proffers that "pill appearance can be an important element of pharmaceutical branding," while also noting that images of a pill design can reinforce "that visual cues like shape and color" are intended to serve as reference points for patients to identify their prescribed medication. *Id.* ¶¶ 16-17. MSN's expert, Todd Clark, in a roundabout way, makes a similar point: that changes in physical attributes from the branded to generic drug can negatively affect therapeutic adherence. Clark Decl. ¶ 17. Patients used to identifying medication based on visual cues should have the option to switch to generic drugs with those same visual cues so as to not disrupt their drug regimen compliance. *Id.* ¶ 18. Dr. Robbins counters that a noticeable change in pill appearance is an important signal to patients that their medication is being switched. Robbins Decl. ¶ 18. Clark rebuts that the benefits offered by continuity of appearance outweigh the hypothetical downside of potential loss of patient autonomy. Clark Decl. ¶ 19.

An MSN executive also explains that in addition to following FDA guidance that generic tablets should have similar physical characteristics to their branded equivalents, MSN picked colors referencing those used for ENTRESTO® pills so that patients can rely on visual cues to identify what drug and dose they are taking. Nithiyanandam Decl. ¶¶ 8-10. The MSN Drug's shape similarity is justified by way of functionality; ovaloid-shaped pills are easier to swallow and more cost-effective to manufacture, and it is industry practice to use larger pills to designate higher doses. *Id.* ¶¶ 12-13. Nithiyanandam goes on to explain that MSN mirrored the functional features of ENTRESTO®, but distinguished them just enough based on the small-font letter markings,

marginal size differences, and color-shading distinctions. *Id.* ¶ 15. In sum and substance, MSN contends that it had to copy ENTRESTO® for functionality purposes, but stopped just short of copying it too much to infringe on the trade dress.

The Court credits the position that distinctive identifiers of medications can serve as useful visual cues for patients, particularly more vulnerable populations such as the elderly or others with comorbidities, and that familiarity with a medication to be taken in seeming perpetuity has an element of functionality. Simultaneously, the Court is wary of expanding this concern across every widely available drug. The functionality doctrine cannot stand for the broader proposition that any distinctive look and feel of a pill means generic brands are free to wholesale copy them under the guise of ensuring patients, whose medication is prescribed by doctors, know what they are taking. Simply put, MSN could have just picked different colors. Or different shapes. Or different sizes.

The Court understands MSN's reliance on *Shire* and takes note of Novartis's omission of it from its moving brief. But the Court's diversion from *Shire*'s holding has less to do with the fact that a controlled substance was uniquely at issue in that case, and more to do with the practical distinctions here. Adderall dosing is more involved. Many patients "may take multiple daily dosages of different strength." *Shire*, 329 F.3d at 354. Safety and compliance is also at greater issue in cases of children, whose doses may be dispensed through non-medical intermediaries. *Id.* at 355. ENTRESTO® patients need not distinguish between daily doses, because the patients remove previous ones from their medication cycle after they adjust to a different dosage. D.E. 17-1 ¶¶ 31-32 ("Nayeri Reb. Decl."). They are taking one type of pill in a day.

As to MSN's position that similarities in physical attributes between drugs helps reduce medication errors, increases therapeutic adherence, and maintains placebo effects, Clark Decl. ¶ 50, the Court notes that "regardless of whether the generic is identical in appearance to the brand

name, the patient ought to be-and usually is-told that a generic medication is now being dispensed." *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Labs.*, 532 F. Supp. 1040, 1047 (D.N.J. 1980). The patient will be aware of the substitution, *id.*, and the Court is unpersuaded that mirroring—entirely or substantially—the appearance of a pill so that patients associate their new medication with the old one means that the initial distinctive appearance is functional. Having found that Novartis has met its burden in demonstrating that the trade dress is likely not functional, the Court turns to whether it has done so for secondary meaning.[2]

2. Novartis has sufficiently demonstrated secondary meaning

Novartis must next show that "in the minds of the public," the primary significance of the trade dress is "to identify the source of the product rather than the product itself." *Wal-Mart Stores, Inc. v. Samara Bros., Inc.*, 529 U.S. 205, 211 (2000) (quoting *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 851 n.11 (1982)) (internal marks omitted). Courts consider factors such as "the extent of sales and advertising leading to buyer association, length of use, exclusivity of use, the fact of copying, customer surveys, customer testimony, the use of the mark in trade journals, the size of the company, the number of sales, the number of customers, and actual confusion" in determining whether secondary meaning exists. *Ford Motor Co. v. Summit Motor Prods., Inc.*, 930 F.2d 277, 292 (3d Cir. 1991).

Novartis has adequately demonstrated the size of the company, the number of sales, and the number of customers. *Id.* It is one of the most well-known global pharmaceutical companies

[2] The Court does not find that the trade dress is generic. Opp'n at 16. In trade dress law "the inquiry into functionality resembles the genericness inquiry in trademark law." *Duraco Prods., v. Joy Plastic Enters., Ltd.*, 40 F.3d 1431, 1442 (3d Cir. 1994). And the Court agrees with Novartis that the relevant market is Novartis's competitors. Reply at 6 (citing *McNeil Nutritionals, LLC v. Heartland Sweeteners LLC*, 566 F. Supp. 2d 378, 390 (E.D. Pa. 2008)). Obviously, there is a finite amount of shapes and sizes that pills can come in. Opp'n at 17. But the Court is satisfied that enough distinctions exist to determine that ENTRESTO® is not generic. Mot. at 18.

with net sales exceeding $45.4 billion in 2023. D.E. 4-3 ¶¶ 6 ("Miller Decl."). It is estimated to have helped over 284 million people worldwide in 2023. *Id.* As to ENTRESTO® specifically, it has generated more than $10.5 billion in cumulative net sales in this country between 2015 and 2023. *Id.* ¶ 26. Novartis estimates that over 2.5 million people have used ENTRESTO® to help with heart failure. *Id.* ¶ 25. MSN's opposition focuses primarily on exclusivity of use and buyer association, which the Court will address in turn.

First, although the shape, size, and colors of ENTRESTO® *alone* do not achieve secondary meaning, the Court finds that the length and exclusivity of use of the trade dress weighs in Novartis's favor. ENTRESTO® has been the only drug of its kind available to treat patients with heart failure for the last nine years. D.E. 4-5 ¶ 8. MSN does not dispute this, but instead argues that because the trade dress consists of ubiquitous sizes, shapes, and colors, these features cannot be used to identify Novartis. Opp'n at 19. Of course, color alone is not inherently distinctive, *Wal-Mart*, 529 U.S. at 212, but MSN seems to just repackage its argument about genericness here. And color, "in combination with other characteristics," can be protectable. *See Smithkline Beckman Corp. v. Pennex Prods. Co., Inc.*, 605 F. Supp. 746, 750 (E.D. Pa. 1985). Under MSN's theory, *no* drug could ever receive trade dress protection because there is a finite universe of size, shape, and color options. ENTRESTO® is "the number one branded treatment for heart failure prescribed by cardiologists" and has been on the market since 2015. Miller Decl. ¶¶ 19-20. The Court is satisfied that Novartis's continuous marketing of this trade dress weighs in favor of the exclusivity and length elements. *See Ciba-Geigy Corp. v. Bolar Pharm. Co., Inc.*, 747 F.2d 844, 852 (3d Cir. 1983).

Second, MSN argues that, despite Novartis's expansive marketing campaign, it has not adequately shown buyer association with ENTRESTO®. Opp'n at 19-20. Courts do "place

particular weight in customer surveys and testimony because, though they 'are not dispositive, they are the only direct evidence of secondary meaning.'" *Richardson v. Cascade Skating Rink*, No. 19-8935, 2024 WL 3841942, at *8 (D.N.J. Aug. 16, 2024) (quoting *King of Prussia Dental Assocs., Ltd. v. King of Prussia Dental Care, LLC*, No. 19-1688, 2019 WL 2240492, at *12 (E.D. Pa. May 23, 2019)). Novartis does offer very little by way of direct consumer testimony. But it does offer testimony that a prescriber "recognize[d] Entresto just by seeing the pills." Nayeri Decl. ¶ 20.

The Court also disagrees with MSN's characterization of Novartis' marketing materials as highlights of the doses associated with each pill to the exclusion of the pills' source. Opp'n at 20. Although the marketing materials often provide instructions on how to take the trio of doses, *see, e.g.*, D.E.s 4-54, 4-55, 4-58, these materials have "routinely featured the [pills'] physical appearance in pictures as well as described them in words," *Ciba-Geigy Corp. v. Bolar Pharm. Co., Inc.*, 547 F. Supp. 1095, 1101 (D.N.J. 1982), *aff'd*, 747 F.2d 844. The Court fails to see how instructions on initiating dosing washes away "promotional efforts . . . not only to familiarize" consumers with the name ENTRESTO® "but also with [ENTRESTO®'s] appearance." *Boehringer*, 532 F. Supp. at 1056. Accordingly, the Court finds that Novartis has met its burden and demonstrated the trade dress has likely achieved secondary meaning.

3. Likelihood of confusion

To determine the final element of a trade dress infringement claim, courts in this district use the Third Circuit's ten-factor test, known as the *Lapp* factors:

> (1) the degree of similarity between the plaintiff's trade dress and the allegedly infringing trade dress;
>
> (2) the strength of the plaintiff's trade dress;
>
> (3) the price of the goods and other factors indicative of the care and attention expected of consumers when making a purchase;

(4) the length of time the defendant has used its trade dress without evidence of actual confusion arising;

(5) the intent of the defendant in adopting its trade dress;

(6) the evidence of actual confusion;

(7) whether the goods, though not competing, are marketed through the same channels of trade and advertised through the same media;

(8) the extent to which the targets of the parties' sales efforts are the same;

(9) the relationship of the goods in the minds of consumers because of the similarity of function;

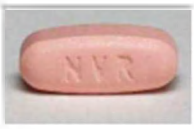
(10) other facts suggesting that the consuming public might expect the plaintiff to manufacture a product in the defendant's market, or that the plaintiff is likely to expand into that market.

McNeil, 511 F.3d at 358 (citing *Freedom Card, Inc. v. JPMorgan Chase & Co.*, 432 F.3d 463, 471 (3d Cir. 2005), further citing *Interpace Corp. v. Lapp, Inc.*, 721 F.2d 460, 463 (3d Cir. 1983)).

Factors 4 and 6 are neutral because MSN has not yet launched the MSN Drug. Mot. at 27. The Court addresses the remaining factors as follows.

a. Factor 1: degree of similarity

There is no question that the two trade dresses are strikingly similar.

Image of ENTRESTO® Tablet			
Image of MSN's Tablet[52]			
Dosage	24/26 mg	49/51 mg	97/103 mg

Compl. ¶ 93.

This is true despite the different markings on the pills, because "[t]he proper test is 'not side-by-side comparison' but 'whether the labels create the same overall impression when viewed separately.'" *Kos*, 369 F.3d at 713 (quoting *Fisons Horticulture, Inc. v. Vigoro Indus., Inc.*, 30 F.3d 466, 477 (3d Cir. 1994)). This factor weighs in favor of Novartis.

b. Factor 2: strength of trade dress

MSN makes the same arguments regarding functionality and secondary meaning with respect to the strength of the trade dress. Opp'n at 23. The Court adopts its reasoning regarding these arguments, *supra*, Sections IV.A.1-2, and finds this factor favors Novartis.

c. Factor 3: consumer care in purchase

The Court agrees with MSN that because the products at issue are prescription medications, the relevant market consists primarily of medical professionals, not consumers. Opp'n at 24; *see Astrazeneca AB v. Dr. Reddy's Labs., Inc.*, 145 F. Supp. 3d 311, 317 (D. Del. 2015). This factor weighs in favor of MSN.

d. Factor 5: intent to infringe

Although awareness of Novartis's trade dresses does not demonstrate bad faith, the Court still finds this factor weighs in Novartis's favor. The Court already rejected MSN's functionality argument, *supra*, Section IV.A.1, so it declines to adopt MSN's position that the evidence unequivocally demonstrates that the similar appearances were driven by functional and regulatory considerations. Opp'n at 25. While the functionality arguments necessarily overlap with those demonstrating an interest in providing visual cues to patients shifting from a branded drug to a generic drug, it does also demonstrate that MSN intended for the pills to look similar. The totality of the circumstances here results in this factor favoring Novartis. *Astrazeneca*, 145 F. Supp. 3d at 317.

e. Factors 7-10: competition and overlap

The Court is persuaded by the District Court of Delaware's analysis in dealing with a branded product and generic, also finding that "[Novartis] and [MSN] are still competing in the same market for the same consumers in the first instance, even if [MSN] is ultimately competing against other generics once the decision to buy a generic has been made." *Id.* at 318. These factors

weigh in favor of Novartis. Accordingly, Novartis has demonstrated a likelihood of confusion and a likelihood to prevail on its trade dress infringement claim.

4. Irreparable harm

"[A] party seeking a preliminary injunction in a Lanham Act case is not entitled to a presumption of irreparable harm but rather is required to demonstrate that she is likely to suffer irreparable harm if an injunction is not granted." *Ferring Pharm., Inc. v. Watson Pharm., Inc.*, 765 F.3d 205, 217 (3d Cir. 2014).[3] Novartis argues that it will suffer irreparable harm through loss of control over its reputation (if MSN's drug is defective) and loss of trade in the form of lost sales (if patients request refills of the MSN Drug, instead of ENTRESTO®). Mot. at 37-38. MSN counters that Novartis's multi-year delay in bringing this action militates against injunctive relief and that its reputational harm theory is too speculative. Opp'n at 34-35.

a. The delay here does not vitiate irreparable harm

Third Circuit caselaw "may imply that inexcusable delay"—*i.e.,* not attributable to negotiations between the parties—"could defeat the presumption of irreparable harm in an appropriate case[.]" *Kos*, 369 F.3d at 727. Though the parties dispute the timeline of Novartis's knowledge of the MSN Drug's appearance, whether Novartis did in fact delay its request for injunctive relief is "most relevant for purposes of the Court's consideration of irreparable harm." *Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd., Inc.*, 99 F. Supp. 3d 461, 504 (D.N.J. 2015).

MSN represents that in the course of the parties' patent claim litigation, MSN produced to Novartis a complete copy of its ANDA, including comparator images of the drugs, in 2020. D.E. 13-2 ¶ 21. It also states that it provided Novartis physical samples of MSN's pills for testing in

[3] Novartis misstates the law on this point, arguing it is entitled to a presumption of irreparable harm. Mot. at 37. The Third Circuit clarified the standard for irreparable harm in Lanham Act cases. *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 203 (3d Cir. 2014).

January 2021. *Id.* ¶ 22. Nonetheless, MSN avers, Novartis never raised concerns with the appearance of MSN's pills. *Id.* ¶ 23. If this information is accurate, it would assuredly counsel against a finding of irreparable harm.

However, Novartis provides further context; the ANDA was produced in that MDL "confidential[ly] pursuant to Delaware Local Rule 26.2." D.E. 17-3 ¶ 18 (citing D.E. 13-10 at 1). Delaware Local Rule 26.2 states that if documents are deemed confidential by the producing parties who have not stipulated to a confidentiality agreement, disclosure is limited to trial counsel and where appropriate, those who have been admitted *pro hac vice*, and the individuals remain "under an obligation to keep such documents confidential and to use them **only for the purpose of litigating the case**." (emphasis added). On September 18, 2020, Judge Stark entered a protective order in the MDL, designating "abbreviated new drug applications (ANDAs) and related FDA correspondence, Drug Master Files, test data relating to physical and/or chemical properties, and materials concerning research and development" as attorneys' eyes only and limiting disclosure to those designated as a qualified person, including specific people involved in or retained for the purpose of that litigation. *Id.* ¶¶ 11-12. The protective order further limited the use of protected information to the MDL actions. *Id.* ¶ 16.

True, practically speaking, Novartis has known about the MSN Drug's purported similar appearance to ENTRESTO® for many years. And the Court is not naïve to a multi-district strategy of litigation based on numerous legal theories to prevent the MSN Drug from hitting the market. But for purposes of *this* case, at earliest, someone from Novartis could have learned about the MSN Drug's physical appearance through a written description of the drug in an exhibit filed in separate litigation on August 6, 2024. *Id.* ¶ 28. At earliest, images of the drug were seen on August

9, 2024, during oral argument in the MDL, though even that visual would presumably be covered by the protective order limiting its use to those actions. *Id.* ¶ 29.

The exhibit describing the MSN Drug's physical appearance is fair game, as it was produced in *Novartis Pharm. Corp. v. Becerra*, No. 24-2234, 2024 WL 3823270 (D.D.C. Aug. 13, 2024), which was not constrained by the protective order in the Delaware MDL. A persuasive argument can be made that a detailed written description of the dimensions, colors, and shapes of a drug is sufficient for purposes of determining whether a trade dress has been copied. Nonetheless, given the complexities of this case and the fact that the MSN Drug has not yet gone to market, the Court does not find the five-month delay precludes a finding of irreparable harm. Having so found, the Court turns to the actual theory of irreparable harm.

b. Theory of reputational harm

"Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill" and irreparable harm "can also be based on the possibility of confusion." *S & R Corp. v. Jiffy Lube Intern., Inc.*, 968 F.2d 371, 378 (3d Cir. 1992). The *Becerra* court conducted a well-reasoned rejection of such a speculative theory of harm "that a brand-name manufacturer will lose general customer goodwill due to the deficiencies of a generic competitor." 2024 WL 3823270, at *6. However, that case involved FDA's approval of the MSN Drug. Instead, the Court is bound by a recognized theory of irreparable harm of "lack of control which potentially might result in a damaged reputation." *Opticians Ass'n of Am. v. Ind. Opticians of Am.*, 920 F.2d 187, 195 (3d Cir. 1990). Relatedly, although the Court does not find that MSN necessarily intended to create a false impression that the MSN Drug is an authorized generic, rather than a bioequivalent, it finds the holding in *Astrazeneca* persuasive, that a misplaced affiliation with Novartis (and ENTRESTO®) "puts at risk [Novartis's] reputation in the event of quality or safety issues with [MSN's] generic."

2015 WL 7307101, at *5. Accordingly, Novartis has demonstrated a likelihood of irreparable harm.

5. Harm to defendants and public interest

Having found the "gateway factors" in Novartis's favor, the Court must turn to the remaining two factors and determine in its discretion if all four balance in favor of granting injunctive relief. *Reilly*, 858 F.3d at 179. There is no question that MSN would suffer significant hardship if enjoined. Opp'n at 36. It would lose its "first mover advantage" and face financial, research, and development setbacks. *Id.* The Court is also mindful of the societal benefits of affordable alternatives to brand-name drugs and laments obstacles to such access. *See Otsuka*, 99 F. Supp. 3d at 507. However, it is axiomatic that "the injury a defendant might suffer if an injunction were imposed may be discounted by the fact that the defendant brought that injury upon itself." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 596 (3d Cir. 2002). As noted *supra*, MSN could have distinguished its pills. Accordingly, on balance, a preliminary injunction is warranted and the Court will **GRANT** a preliminary injunction.

B. Trademark Infringement[4]

1. There is no likelihood of confusion with the NOVADOZ mark

The elements for a trademark infringement claim under the Lanham Act are the same for those under New Jersey statutory and common law. *J&J Snack Foods, Corp. v. Earthgrains Co.*, 220 F. Supp. 2d 358, 374 (D.N.J. 2002). To establish such a claim, "a plaintiff must show that (1) it owns the mark; (2) its mark is valid and legally protectable; and (3) the Defendant's use of the

[4] Trademark infringement and unfair competition share the same elements and analysis. *Checkpoint Sys., Inc. v. Check Point Software Tech., Inc.*, 269 F.3d 270, 279 (3d Cir. 2001).

mark to identify its goods or services is likely to create confusion concerning the origin of those goods or services." *Id.* MSN does not contest the first two elements, and instead argues that there is no likelihood of confusion between the parties' marks. Opp'n at 29. After analyzing the *Lapp* factors, the Court agrees. As a threshold matter, Novartis adopts its same position of neutrality on factors 4 and 6 as argued in its trade dress position. Mot. at 27, 33.

a. Factor 1: degree of similarity

NOVADOZ is likely not confusingly similar to NOVARTIS. Novartis's arguments hinges on the fact that both words have three syllables, begin and end with similar sounds, and are coined words. Mot. at 31 (citing *Kos*, 369 F.3d at 712-15). In cases where the words contained the "same dominant syllable," they still gave the overall impression of similarity. *Sabinsa Corp. v. Creative Compounds, LLC*, 609 F.3d 175, 184 (3d Cir. 2010) (ForsLean and Forsthin gave overall similar impressions, and notably, the words "lean" and "thin" are interchangeable terms to consumers). The Court is not persuaded that there is a "similarity between the visual appearance" or aural similarity of the words NOVADOZ and NOVARTIS. *CPC Intern., Inc. v. Caribe Food Distribs.*, 731 F. Supp. 660, 665 (D.N.J. 1990) (Mazorca and Mazola look and sound alike). The marks are distinguishable in "'appearance, sound and meaning[].'" *Checkpoint Sys.*, 269 F.3d at 281 (quoting *Harlem Wizards Entm't Basketball, Inc. v. NBA Props., Inc.*, 952 F. Supp. 1084, 1096 (D.N.J. 1997)). The Court is also less persuaded that the "Doz" portion of NOVADOZ will be perceived to derive from Novartis's previous generics division, Sandoz. Mot. at 31. It is satisfied with MSN's attestation that the name is a combination of "Nova," meaning bright new star, and "doz," which invokes the word "dose." D.E. 13-2 ¶ 5. This factor weighs against Novartis.

b. Factor 2: strength of mark

"To evaluate the strength of the mark, courts look at '(1) the mark's distinctiveness or conceptual strength (the inherent features of the mark) and (2) [the mark's] commercial strength

(factual evidence of marketplace recognition).'" *What a Smoke, LLC v. Duracell U.S. Operations, Inc.*, No. 19-16657, 2024 WL 1327976, at *8 (D.N.J. Mar. 27, 2024) (quoting *Freedom Card*, 432 F.3d at 472). There is no dispute as to the ubiquity of the NOVARTIS trademark, given the company's massive profits and billions of dollars spent on marketing. Mot. at 32. However, as MSN points out, many marks begin with "Nov" or "Nova." Opp'n at 30 (citing D.E. 13-26). Novartis curiously dismisses third-party uses of the first three or four letters of the NOVARTIS mark and argues they do not undermine its strength, when it just made the argument that MSN has infringed because the first four letters of its mark are the same. Reply at 10. The Court is persuaded that there is enough evidence of third-party use of the prefix "Nov" or "Nova" so as to diminish the strength of the NOVARTIS mark. *Petro Stopping Ctrs., L.P. v. James River Petroleum, Inc.*, 130 F.3d 88, 94 (4th Cir. 1997); D.E. 13-26 (hundreds of trademarks with similar prefix). This factor weighs against Novartis.

c. Factor 3: consumer care in purchase

This factor weighs in favor of MSN for the same reasons explained *supra*, Section IV.A.3.c.

d. Factor 5: intent to infringe

Novartis also adopts its argument on this element as proffered in its trade dress claim. Mot. at 27, 33. Previously, Novartis argued that MSN's knowledge of the trade dress demonstrated its bad faith and intention to copy the design. *Id.* at 27. The Court is unconvinced by Novartis's argument that MSN "hid" its planned use of NOVADOZ in connection with the MSN Drug by initially producing a label with the MSN mark. Reply at 11. It is satisfied with MSN's explanation for the name for purposes of the preliminary injunction motion, D.E. 13-2 ¶ 5, and notes that the name has been used since 2018. Opp'n at 2. This factor favors MSN.

e. Factors 7-10: competition and overlap

The Court adopts its discussion *supra*, Section IV.A.3.e and finds these factors weigh in favor of Novartis, which evens the score. However, given "[t]he single most important factor in determining likelihood of confusion is mark similarity," which the Court found against Novartis, on balance, Novartis has not demonstrated a likelihood of confusion. *A & H Sportswear, Inc. v. Victoria's Secret Stores, Inc.*, 237 F.3d 198, 216 (3d Cir. 2000). Accordingly, the Court finds that Novartis is not likely to succeed on its trademark infringement claim (and resultingly, its state law claims) and will **DENY** its Motion to this extent.[5]

V. CONCLUSION

For the reasons stated above, the Court will **GRANT in part** and **DENY in part** Novartis's Motion for Preliminary Injunction. An appropriate Order accompanies this Opinion.

Dated: March 17, 2025

Evelyn Padin, U.S.D.J.

[5] The Court recognizes that its holding above will enjoin MSN from putting the MSN Drug to market, functionally enjoining the use of the NOVADOZ name as well.

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS AG and NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. NOVADOZ PHARMACEUTICALS LLC, *et al.*, Defendants.	No. 25cv849 (EP) (JRA) **ORDER**

Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation move for a preliminary injunction against Defendants MSN Laboratories Private Limited, MSN Pharmaceuticals Inc., and Novadoz Pharmaceuticals LLC for alleged infringement of Plaintiffs' trademark and trade dress rights. D.E. 4 ("Motion"). Having reviewed the parties' submissions and all other relevant items on the docket, and having determined that oral argument is not necessary,

IT IS, on this **17th** day of March 2025, for the reasons set forth in the accompanying Opinion,

ORDERED that Plaintiffs' Motion for Preliminary Injunction, D.E. 4, is **GRANTED in part** and **DENIED in part**; and it is further

ORDERED that Plaintiffs have not demonstrated a likelihood to succeed on the merits of their trademark infringement and state law claims; and it is finally

ORDERED that Defendants are **PRELIMINARY ENJOINED** from manufacturing, producing, distributing, circulating, selling, marketing, offering for sale, advertising, promoting, or displaying the MSN Drug, in a manner likely to infringe on Plaintiffs' trade dress.

Evelyn Padin, U.S.D.J.